REMARKS/ARGUMENTS

The rejections presented in the Office Action dated March 14, 2007 (hereinafter Office Action) have been considered. Claims 1-40 and 78-94 remain pending in the application. Claims 81-94 have been withdrawn by the Examiner for being directed to a non-elected invention. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claim 2 has been canceled without prejudice or disclaimer. Claims 1, 3, 14, 18-20, 25, 32, 78, and 79 have been amended.

Support for the amendments to independent claims 1, 32, 78, and 79 concerning a first configuration using only subcutaneously electrodes can be found in now canceled dependent claim 2, among other locations.

Support for the amendments to independent claims 1 and 78 concerning a first configuration operable with no intrathoracic electrodes are attached and a second configuration operable with intrathoracic electrodes are attached can be found in the Specification on page 52, line 17 – page 53, line 3; page 4, lines 4-9; page 19, lines 8-9; page 51, lines 1-23; and page 8, lines 9-21, among other locations.

Support for the amendment to claim 32 concerning parallel operation can be found on page 21, lines 5-10, among other locations.

Support for the amendments to claims 1 and 32 concerning program instructions can be found on page 61, lines 13-16; memory and control systems on page 31, lines 2-4 and lines 16-20; page 34, line 35 – page 35, line 3; and page 37, lines 22-23; among other locations.

The amendments to claims 3, 14, 18-20, and 25 carry though the amendments to claim 1. Any other amendments to the claims include subject matter that was already inherent in the claims or are otherwise properly supported in the Specification. Accordingly, no new matter is added.

The Specification stands objected to as failing to provide proper antecedent basis for the claimed subject matter of claims 78-80, under 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Specifically, the Office Action states that the means clauses recited in claims

78-80 lack antecedent basis. Further, claims 78-80 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The Applicant respectfully submits that the Specification fully complies with 37 CFR 1.75(d)(1) and MPEP § 608.01(o), and that claims 78-80 fully comply with 35 U.S.C. §112, second paragraph.

MPEP § 608.01(o) states that the "meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import." Furthermore, 37 CFR 1.75(d)(1) recites that the "claim or claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description" (emphasis added).

The Applicant respectfully submits that the terms and phrases of the means clauses of claims 78-80 do have clear support in the Specification. For example, clear support for the subject matter of claims 78-80 can be found in Figs. 4, 7, 8, 12, 16, 19, and 23, and the corresponding textual matter of the Specification, as well as other locations. The Applicant respectfully requests specific identification of any terms or phrases that do not have clear support in the Specification.

Considering that the terms and phrases of claims 78-80 have clear support within the Specification, antecedent basis is not required for compliance with 37 CFR 1.75(d)(1) and MPEP § 608.01(o). As such, the Applicant respectfully requests reconsideration and withdrawal of the objection to the Specification.

MPEP § 2181 makes clear that the PTO may require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) "[i]n the situation in which the written description only implicitly or inherently sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function." *Emphasis added.*

Importantly, amendment to the specification in this regard is not required if the disclosure explicitly (rather than implicitly) sets forth the structure, material, or acts

corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs. The Applicant asserts that its specification explicitly sets forth the structure, material, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs.

MPEP § 2181 cites *B. Braun Medical, Inc. v. Abbott Lab.*, 124 F.3d 1419 (Fed. Cir. 1997) as pertinent to this analysis. In *B. Braun Medical,* 124 F.3d at 1424, the court evaluated the adequacy of the disclosure and concluded that the specification explicitly set forth the structure, materials, or acts corresponding to a means- (or step-) plus-function in a manner that would clearly comply with 37 CFR 1.75(d). In examining the written description, the court found clear and unambiguous reference to such structure at issue.

The Applicant respectfully submits that the terms and phrases of the means clauses of claims 78-80 do have clear support in the Specification, and that the Specification explicitly sets forth the structure corresponding to each of the means-plus-function elements. For example, clear support for the subject matter of claims 78-80 can be found in Figs. 4, 7, 8, 12, 16, 19, and 23, and the corresponding textual matter of the Specification, as well as other locations.

The proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. See *Atmel Corp. v. Information Storage Devices*, Inc., 198 F.3d 1374, 1381 (Fed. Cir. 1999).

The Applicant respectfully submits that the structure corresponding to the means-plus-function limitations of claims 78-80 is disclosed in the Specification in a way that one skilled in the art would understand what structure will perform the recited functions. As such, the Applicant respectfully submits that the Applicant is not required to amend the Specification to identify all of the elements that correspond to the means elements of claims 78-80, absent some showing that a specific means for a recited function is unrecognizable by one skilled in the art. Even so, the Applicant respectfully submits that at least some of the means for at least some of the recited functions of claims 78-80 can be found in Figs. 2-

4, 8, and 10-12, and the corresponding textual matter of the Specification, as well as in other locations.

Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the § 112, paragraph 2, rejections of claims 78-80.

Claim 20 stands rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Specifically, claim 20 stands rejected for reciting heart chambers as part of the invention. The Applicant has amended claim 20 to make clear that heart chambers themselves, as part of the human body, are not being claimed. The Applicant respectfully submits that defining structures in terms of attributes they must possess, such as two lead electrodes being configured to be disposed in a single heart chamber, has long been sanctioned in the case law. (See *In re Venezia*, 530 F.2d 956, 189 U.S.P.Q. 149 (CCPA 1976)). Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the § 101 rejection of claim 20.

Claims 1-40 and 78-80 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Office Action states that independent claims 1, 32, 78, and 79 include embodiments, not disclosed in the Specification, where stimulation and sensing is performed using a single electrode. (Page 4). The Applicant respectfully disagrees with the Examiner regarding the purported lack of enablement, as the independent claims prior to amendment need not be construed in a manner that would require use of only a single electrode for stimulation and sensing. Notwithstanding same, the Applicant has amended claims 1 and 32 such that all configurations explicitly operate with at least two electrodes. The Applicant respectfully submits that claims 78 and 79 do not include such single electrode operation embodiments within the scope of the claims.

Therefore, the Applicant respectfully requests reconsideration and withdrawal of the §112, first paragraph, rejections of claims 1-40 and 78-80.

Claims 1-6, 40, 78-80 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,148,230 to *KenKnight* (hereinafter *"KenKnight"*).

The Applicant notes that while claims 32-39 were not explicitly rejected by *KenKnight*, it appears that claims 32-39 were intended to be rejected under the *KenKnight* reference. (See Page 6 of the Office Action). Accordingly, the Applicant will address the rejection as if claims 32-39 are rejected under § 102(b) via *KenKnight*. The Applicant's discussion of claims 32-39 is to be considered, for any purpose, only to the extent that it was intended that claims 32-39 be rejected by *KenKnight*.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *KenKnight* does not teach each and every element of independent claims 1, 32, 78, and 79, and therefore fails to anticipate these claims.

The Applicant's independent claim 1 recites, among other features, a first configuration using only two or more subcutaneous electrodes in the absence of at least one lead being received by a lead interface, and operation in a second configuration using at least one or more lead electrodes with the at least one lead received by the lead interface, a controller of the system implementing cardiac activity sensing and stimulation in each of the first and second system configurations, respectively.

The Applicant's independent claim 32 recites, among other features, a first configuration using only two or more subcutaneous electrodes; and operation in a second configuration using at least one or more lead electrodes with at least one lead received by the lead interface, wherein the controller is configured to execute program instructions stored in memory to cause the system to implement cardiac activity sensing and stimulation in each of the first and second system configurations, respectively.

The Applicant's independent claim 78 recites, among other features, means for operating the system in a first configuration using only subcutaneous, non-intrathoracic electrodes coupled to the sensing and generating means in the absence of the at least one

lead being coupled to the sensing and generating means; and means for sensing cardiac activity and delivering the cardiac stimulation therapy in each of the first and second configurations.

The Applicant's independent claim 79 recites, among other features, means for acquiring, using a second configuration, performance data associated with performance of a particular function by a first configuration.

The Applicant respectfully submits that *KenKnight* does not teach a configuration using only subcutaneous electrodes for sensing cardiac signals and delivering cardiac stimulation, among other features included in the independent claims.

KenKnight discloses an implantable cardiac defibrillator 18 with a lead 20 carrying two subcutaneous cardiac sensing electrodes 22 and 24, the sensing electrodes being in spatially separate locations when implanted within a patient. (Col. 3, Lines 1-6). *KenKnight* discloses that spatial separation of cardiac sensing electrodes is important because they "gather a greater volume of heart tissue." (Col. 1, Lines 36-40). As such, *KenKnight's* implantable cardiac defibrillator 18 senses cardiac signal using at least one of the subcutaneous electrodes. (Col. 4, Lines 16-19). *KenKnight* further discloses that the lead 20 can optionally include a defibrillation electrode 26. (Col. 3, Lines 6-7).

KenKnight's implantable cardiac defibrillator 18 is disclosed as including at least one defibrillation electrode on a transveneous catheter 10, the transveneous catheter 10 being inserted into a patient's heart 4. (Col. 3, Lines 20-22 and Lines 29-31). Defibrillation pulses are delivered using a defibrillation electrode on the transveneous catheter 10 and one complementary electrode, the complementary electrode being on the same transveneous catheter 10, on a different transveneous catheter, a heart contacting patch electrode, a can electrode, on the subcutaneous lead, or in another location. (Col. 3, Lines 33-40).

KenKnight does not disclose any configurations using only subcutaneous electrodes for both sensing and stimulation, as recited in the first configuration of independent claims 1, 32, 78, and 79. *KenKnight* does not disclose that the implantable cardiac defibrillator 18 includes a configuration where cardiac stimulation is performed using only subcutaneous electrodes. Moreover, the Applicant respectfully submits that *KenKnight* clearly

contemplates in col. 3, lines 29-36 that delivery of electrical stimulation to the heart requires one of the electrodes of the transvascular catheter 11, even though the complementary electrode does not need be intrathoracic.

For at least the reason that *KenKnight* fails to teach delivery of cardiac stimulation energy using only subcutaneous electrodes, as recited in each of independent claims 1, 32, 78, and 79, *KenKnight* cannot anticipate these claims.

Moreover, *KenKnight* does not disclose a configuration operable when a transvenous lead is not attached to the implantable cardiac defibrillator 18.

Each of the Applicant's independent claims 1 and 78 recite, among other features, some variation of a first configuration using only the two or more subcutaneous electrodes in the absence of the at least one intrathoracic lead being received by the lead interface.

KenKnight does not disclose any embodiments that have a coupling interface for, but lack, an intrathoracic lead, and a sensing and stimulating configuration operable in the absence of the intrathoracic lead. For at least this reason, the Applicant respectfully submits that *KenKnight* fails to teach all elements and limitations of independent claims 1 and 78, and consequently cannot anticipate these claims.

The Applicant's independent claim 32 recites, among other features, that the controller is configured to execute program instructions stored in memory to cause the system to implement cardiac activity sensing and stimulation in each of the first and second system configurations, respectively, and operate the first and second configurations in parallel such that the second configuration acquires performance data associated with performance of a particular function of the first configuration.

The Applicant's independent claim 79 recites, among other limitations, means for acquiring, using a second configuration, performance data associated with performance of a particular function by a first configuration.

The Applicant respectfully submits that even though *KenKnight* discloses collecting cardiac electrical activity information (Col. 4, Lines 32-33), *KenKnight* does not disclose acquiring performance data associated with the performance of the implantable cardiac defibrillator 18 in performing a particular function using a particular configuration.

Moreover, *KenKnight* does not disclose using one configuration to acquire performance data of another configuration, the performance data associated with the performance of the other configuration in sensing (claim 33), tachyarrhythmia detection (claims 34 and 36), bradycardia detection (claim 35), or stimulus waveform generation and stimulus waveform delivery (claim 37).

Further, it is well established that a controller, processor or computer that carries out instructions, such as those that are implemented by Applicant's controller of the claimed subject matter defines a physically (i.e., structurally) new device. For example, as is discussed in *WMS Gaming, Inc. v. Int'l Game Technology*, 184 F.3d 1339, 1348 (Fed. Cir. 1999):

> A general purpose computer, or microprocessor, programmed to carry out an algorithm creates "a new machine, because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software." *In re Alappat,* 33 F.3d 1526, 1545, 31 USPQ2d 1545, 1558 (Fed.Cir.1994) (en banc); *see In re Bernhart,* 57 C.C.P.A. 737, 417 F.2d 1395, 1399-1400, 163 USPQ 611, 615-16 (CCPA 1969) ("[I]f a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged."). The instructions of the software program that carry out the algorithm electrically change the general purpose computer by creating electrical paths within the device. These electrical paths create a special purpose machine for carrying out the particular algorithm.

The Applicant respectfully submits that *KenKnight* fails to teach, explicitly or implicitly, a controller configured to execute program instructions to implement the operations recited in Applicant's claimed subject matter.

For each of the reasons discussed above, the Applicant respectfully submits that *KenKnight* does not teach each and every element and limitation of independent claims 1, 32, 78, and 79, nor all limitations of each of dependent claims 33-37.

Dependent claims 2-6, 33-40, and 80, which are dependent from independent claims 1, 32, and 79, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *KenKnight*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the amendments and remarks made in connection with independent claims 1, 32, and 79. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2-6, 33-40, and 80 are also not anticipated by *KenKnight*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1-6, 32-40, and 78-80 as being anticipated by *KenKnight* is not sustainable, the withdrawal of which is respectfully requested.

The Applicant notes that claims 7-31 were not explicitly rejected as being anticipated, nor was the subject matter of these claims discussed in the Office Action in association with an anticipation rejection. Accordingly, the Applicant respectfully requests notification that at least these claims contain allowable subject matter, after withdrawal of the § 112, first paragraph rejection of these claims, as discussed above.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art to the Applicant's claimed subject matter. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.618) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,
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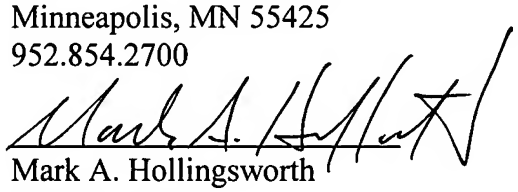
By: 
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